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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,493	04/06/2001	Lenard M. Lichtenberger	96606/15UTL	5746
23873	7590	08/11/2004	EXAMINER	
ROBERT W STROZIER, P.L.L.C			JIANG, SHAOJIA A	
PO BOX 429			ART UNIT	
BELLAIRE, TX 77402-0429			PAPER NUMBER	
			1617	
DATE MAILED: 08/11/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/827,493

Applicant(s)

LICHTENBERGER, LENARD M.

Examiner

Shaojia A Jiang

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 26 July 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.Claim(s) objected to: none.Claim(s) rejected: 1-32 and 46-48.Claim(s) withdrawn from consideration: 33-45.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
SHAOJIA ANNA JIANG  
PATENT EXAMINER

***Advisory Action***

This Office Action is a response to Applicant's response/Remarks after FINAL filed on July 26, 2004. Note that no amendment is filed after FINAL.

5. The rejection of Claims 1-32 and 46-48 made under 35 U.S.C. 103(a) as being unpatentable over DAIFOTIS, et al. (WO 9904773, of record) in view of Lichtenberger et al. (5,763,422, of record), further in view of Hovancik et al. (5,869,471, of record) in the Final Office Action dated February 26, 2004, is maintained.

Applicant's remarks filed July 26, 2004 with respect to this rejection have been fully considered but are unpersuasive for reasons of record stated in the Final Office Action dated February 26, 2004.

As discussed in the Final rejection, motivation to combine the teachings of the prior art to make the present invention is seen. The claimed invention is obvious in view of the prior art.

Again, Dr. Lichtenberger's second declaration herein is ineffective to overcome the 103(a) rejection herein since it is not seen to provide clear and convincing evidence of nonobviousness or unexpected results. The declaration merely presents the testing result for the single particular bisphosphonate, risedronate, in combination with the single particular zwitterionic phospholipid, DPPC, and/or also combining indomethacin (a NSAID), to be administered orally to rats. However, the evidence in the declaration is not commensurate in scope with the claimed invention and does not demonstrate

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criticality of a claimed range of the bisphosphonates (a genus) and zwitterionic phospholipids (a genus) in the claimed composition. See MPEP § 716.02(d).

Nonetheless, the data in diagrams, figures, and tables herein are unclear as to how the graphical, diagram and table presentations herein may be taken to demonstrate unexpected effect in the instant invention. Moreover, the clear explanation of pointing out exactly what facts are established therein and relied upon by applicant is not seen in the declaration. Applicant has the burden to explain the experimental evidence. See *In re Borkowski and Van Venrooy* 184 USPQ 29 (CCPA 1974).

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.  
Patent Examiner, AU 1617  
August 6, 2004